

**Title 19 – DEPARTMENT OF
HEALTH AND SENIOR SERVICES
Division 25 – Missouri State Public Health Laboratory
Chapter 36 – Testing for Metabolic Diseases**

PROPOSED AMENDMENT

19 CSR 25-36.010 Testing for Metabolic and Genetic Disorders. The department is amending the Purpose statement, amending sections (1), (3), (6), adding new sections (5) and (7), and renumbering thereafter.

PURPOSE: This amendment provides further clarification regarding the appropriate collection of specimen for newborn screening, the process for rejecting a screening, the process for objecting to the storage or release of leftover specimen, the responsibility of providers to educate parents about the newborn screening, and establishes a new fee ceiling for the specimen collection.

*PURPOSE: State law requires that all infants be tested for metabolic and genetic disorders as prescribed by the Department of Health and Senior Services. This rule establishes [the metabolic and genetic disorders that each infant shall be tested for and] the collection and submission procedures to be used by health care providers in sending **newborn screening** specimens to the State Public Health Laboratory[. This rule also] **and** establishes the fee for newborn screening.*

(1) As used in this rule---

(A) Newborn screening means the testing of infants for metabolic and genetic disorders pursuant to sections 191.331, [and] 191.332, **and 191.333**, RSMo; [and]

(B) **Parent information sheet means the top sheet of the newborn screening specimen form that is to be detached and handed to the infant's parent or guardian at the time of specimen collection which explains the parent's or guardian's options and process for opting out of the specimen storage and/or release for anonymous research pursuant to section 191.317, RSMo;**

(C) **Specimen storage means the five (5) year storage of the leftover newborn screening specimens at the State Public Health Laboratory after testing has been conducted pursuant to section 191.317, RSMo; and**

(D) **Submitter(s) means a person or persons responsible for collecting specimens under section 191.331, RSMo, for newborn screening tests[:].**

(3) Specimens shall be collected in accordance with instructions on the specimen collection form. **At the time of specimen collection, the submitter shall detach the parent information sheet from the newborn screening collection form and give it to the infant's parent or guardian.** The timing of specimen collection shall be determined by the conditions specified in subsections (3)(A) through (C) below. All specimens shall be sent within twenty-four (24) hours of collection to the State Public Health Laboratory in Jefferson City.

(A) A specimen shall be taken from all infants before being discharged from the hospital or birthing facility regardless of age. A specimen collected between twenty-four (24) and forty-eight (48) hours of [life] **age** is considered optimum for newborn screening. A

second, or repeat, specimen shall be required within fourteen (14) days of *[life]* **age** if the initial specimen was collected before twenty-four (24) hours of *[life]* **age**.

(B) Initial specimens from ill or premature infants shall be collected before a blood transfusion or between twenty-four (24) to forty-eight (48) hours of *[life]* **age**. All ill or premature infants shall have a repeat screen collected between seven (7) to fourteen (14) days of *[life]* **age**. **All infants who are less than thirty-four (34) weeks gestational age or are less than two thousand (2000) grams at birth are recommended to have a third screen collected at twenty-eight (28) days of age.**

(C) If an infant has been transferred from one hospital to another, the records shall clearly indicate if a specimen for newborn screening was collected and submitted. If no specimen was collected, the hospital the infant is transferred to shall collect a specimen and submit it within forty-eight (48) hours of the transfer.

(D) If it is discovered or highly suspected that a child has never received a newborn screen, a newborn screening should be conducted at that time regardless of the child's age.

(5) Parents or guardians who object to the storage or release of their child's leftover newborn screening specimen for anonymous research shall state those objections in writing by submitting a letter to the State Public Health Laboratory Director requesting the remaining specimen to be destroyed, returned to the parents or guardians or stored for five (5) years but not released for anonymous research. This letter shall be sent to the Missouri State Public Health Laboratory, Newborn Screening Laboratory, P.O. Box 570, Jefferson City, MO, 65102-0570. The parents or guardians may submit this request at any point during the five (5) year storage process.

[(5)] (6) The health care provider caring for an infant with an abnormal high-risk test report from newborn screening shall report a definitive diagnosis within thirty (30) days of the date of the diagnosis for that infant to the appropriate contracted follow-up center as contracted by the Department of Health and Senior Services. The department shall prescribe and furnish all necessary reporting forms for this purpose.

(7) The medical professional responsible for the medical care of the infant shall provide newborn screening education to the parents or guardians. Educational materials regarding the newborn screening conducted by the state, including the disorders screened for and the management and treatment of these disorders are made available by the Department of Health and Senior Services. The educational materials may be ordered at www.health.mo.gov/warehouse/e-literature.html or by contacting the Department of Health and Senior Services' Newborn Screening Program at 800-877-6246.

[(6)] (8) Effective *[January 30, 2008]* **July 1, 2015**, a fee of up to *[sixty-five]* **ninety-five dollars** *[(\$65)]* **(\$95)** shall be charged for each specimen collection form used to obtain a newborn screening blood specimen. *[If the State Public Health Laboratory determines a submitted blood specimen to be unsatisfactory for testing, then a replacement specimen collection form will be made available without the fee being imposed.]* The Department of Health and Senior Services may collect the fee from any entity or individual described in **section 191.331.1, RSMo.**

AUTHORITY: sections [191.331 and] 192.006, RSMo 2000, and 191.331 and 191.332, RSMo Supp. [2006] 2014. This rule was previously filed as 13 CSR 50-143.010 and 19 CSR 20-36.010. Original rule filed Sept. 29, 1965, effective Oct. 13, 1965. Amended: Filed April 6, 1967, effective April 16, 1967. Rescinded and readopted: Filed Sept. 30, 1980, effective April 11,*

1981. Rescinded: Filed Aug. 1, 1986, effective Oct. 27, 1986. Readopted: Filed Aug. 4, 1986, effective Oct. 27, 1986. Amended: Filed March 16, 1987, effective May 28, 1987. Amended: Filed Jan. 15, 1993, effective Sept. 9, 1993. Changed to 19 CSR 25-36.010 Jan. 1, 1995. Emergency amendment filed Aug. 4, 1997, effective Aug. 28, 1997, expired Feb. 26, 1998. Amended: Filed Aug. 4, 1997, effective Jan. 30, 1998. Amended: Filed April 9, 2002, effective Oct.30, 2002. Amended: Filed Feb. 1, 2005, effective July 30, 2005. Amended: Filed June 12, 2007, effective Jan. 30, 2008. Amended: Filed

**Original authority: 191.331, RSMo 1965, amended 1985, 1992, 1993, 1995, 1997; 191.332, RSMo 2001, amended 2005; and 192.006, RSMo 1993, amended 1995.*

PUBLIC COST: This proposed amendment will cost state agencies ninety seven thousand six hundred fifty dollars (\$97,650) annually with projected first year fee increase; one hundred forty one thousand eight hundred twenty five dollars (\$141,825) in the aggregate with projected second year fee increase; and up to two hundred twenty three thousand two hundred dollars (\$223,200) in the aggregate annually thereafter with implementation of additional fee increases up to the established fee cap.

PRIVATE COST: This proposed amendment will cost private entities one million three hundred thirty thousand five hundred sixty dollars (\$1,330,560) annually with projected first year fee increase; one million seven hundred thirteen thousand six hundred dollars (\$1,713,600) in the aggregate annually with the projected second year fee increase; and up to two million four hundred nineteen thousand two hundred dollars (\$2,419,200) in the aggregate annually thereafter with implementation of additional fee increases up to the established fee cap.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed rule with the Missouri Department of Health and Senior Services, State Public Health Laboratory, Bill Whitmar, Laboratory Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*